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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/004,686	12/05/2001	Yinghong Yu	13569.0019US01	7614
23552	7590	03/15/2005	EXAMINER	
MERCHANT & GOULD PC P.O. BOX 2903 MINNEAPOLIS, MN 55402-0903			SCHAETZLE, KENNEDY	
			ART UNIT	PAPER NUMBER
			3762	

DATE MAILED: 03/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

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<b>Office Action Summary</b>	<b>Application No.</b> 10/004,686	<b>Applicant(s)</b> YU ET AL.	
	<b>Examiner</b> Kennedy Schaetzle	<b>Art Unit</b> 3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 03 January 2005.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-40 is/are pending in the application.
- 4a) Of the above claim(s) 1-21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 22-28 and 32-38 is/are rejected.
- 7) ☒ Claim(s) 29-31, 39 and 40 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 05 December 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### ***Claim Rejections - 35 USC § 103***

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 22-28 and 32-38 are rejected under 35 U.S.C. 103(a) as obvious over Cunningham (Pat. No. 6,077,236) in view of Ecker et al. (Pat. No. 5,702,427).

Regarding claim 22, Cunningham discloses a cardiac motion sensor unit comprising an acceleration sensing device 2 that generates a signal representative of movement of a cardiac wall, and a conductor device with an elongated insulator body (insulated wires 7 and 8 as discussed in col. 6, lines 47-50) that transmit the signal to an electronic device. Regarding the recitation concerning the use of a connector configured for removable attachment of the motion sensor unit to the electronic device, the examiner notes that, while not explicitly shown, the pacing/sensing lead must have some form of traditional connector device (commonly a connector pin arrangement) if it is to connect to the electronic device 9. Connectors that allow for removable attachment of leads from electronic devices are old and well known in the medical implant arts. Such a feature allows one to more readily replace or update the implant by simply detaching the electronics housing from the lead --a lead which may be difficult to remove due to fibrotic cardiac tissue growth-- and plugging a new unit in. Connectors that provide removable connection of the lead unit to the electronic device housing are so commonplace that the industry has developed standards for their manufacture. One, in fact, would be hard-pressed to find a connector that *didn't* allow for removable attachment. Ecker et al., for example, disclose a typical connector pin arrangement (see Figs. 2-5) that conforms to the IS-1 standard. To incorporate the same ubiquitous arrangement in the Cunningham device would have been seen by ordinarily skilled artisans to be completely and blatantly obvious.

Regarding the term "molded into," the examiner considers such a term to relate to a product-by-process limitation. Such claims are only limited by the structure implied by the steps, and not the step(s) itself. The claimed product appears to be the same or similar to that of the Cunningham device since both products would contain an insulating layer over the conductor. Furthermore, it would not appear to make any difference as to how the insulative material was applied from an operational standpoint. Clearly an insulator body is required to prevent signal interference and shorting of signals between conductors. How such a body is constructed with respect to a conductor is of little consequence to this issue. A related comment applies to claim 25.

Regarding claim 23, limitations relating to the position of structure within the body fail to saliently distinguish over the apparatus of Cunningham which is considered to be capable of such placement simply depending on the size of the vein and the species under treatment.

The limitations set forth in claims 24 and 27 are clearly shown.

Regarding claim 28, note col. 7, lines 25-31.

With reference to claims 32-35, 37 and 38, note the comments made in the rejection of similarly worded claims above.

Regarding claims 26 and 36, Cunningham does not discuss the type of material used to provide the insulation on the conductor device. The examiner took Official Notice in the previous Office Action that polymers are well-known stable, biocompatible insulators and find common use in a wide variety of applications including medical device applications for maintaining electrical isolation of conductors. Since the applicants have failed to traverse this notice, the feature is now taken to be admitted prior art.

### ***Response to Arguments***

3. Applicant's arguments filed January 3, 2005 have been fully considered but they are not persuasive.

The applicants argue that the Cunningham reference (a) does not teach or disclose a conductor molded into an elongated insulator body that transmits signals

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representative of movement of a cardiac wall from the acceleration sensing device, and (b) does not disclose a connector device configured for removable attachment of the motion sensor to the electronic device.

As for the first contention, the examiner had stated in the previous Office Action that the "molded into" language was considered to relate to a product-by-process limitation, with the claims only limited by the structure implied by the steps and not the step(s) itself. The structure implied by the molding step is that of a conductor surrounded by an elongated insulator body (i.e., an insulated wire). Cunningham discloses elongated wires 7 and 8, each of which is surrounded by an elongated insulator body (as best can be seen in Figs. 19 and 20). The act of insulating wires by molding the insulator to the conductor or coating the conductors is an old and well-known process in the lead manufacturing arts and an obvious electrical expediency to provide electrical isolation between the conductors as they travel down the length of the catheter through the catheter lumen.

The applicants further conclude that the examiner's assertion that Cunningham discloses a conductor device with an elongated insulator body does not set forth the elements of the conductor device disclosed in claim 22, but gives no explanation as to why this is so.

Applicants go on to state that the device of Cunningham is nothing more than a "two-wire conductor in simple form." The examiner counters that there is nothing recited in claim 22 that would preclude "two-wire conductors in simple form."

It is additionally argued that because the specification states that wires 7 and 8 run inside the catheter, they cannot be molded into an elongated insulator body. This assertion is not understood since clearly conductive wires 7 and 8 must be insulated within the catheter to prevent shorting. It is unclear why wires cannot be molded into an elongated insulator body simply because they happen to be placed within a catheter lumen.

The applicants further refer to a supposed attempt by the examiner to equate the catheter disclosed by Cunningham to an element of the present invention. This is not understood as well since the examiner has never even mentioned the catheter of the

Cunningham device when rejecting the claims. The examiner is relying upon the wire insulation itself and not the catheter through which the insulated wires run.

Further arguments by the applicant refer to portions of the specification in an attempt to distinguish the apparatus over the prior art. Limitations in the specification cannot be read into the claims. The applicants must rely upon the language recited within the claims and will not be permitted to import limitations from the specification. It should further be noted that the claim language does not come under the purview of §112, 6<sup>th</sup> paragraph. The examiner is therefore not limited to structure disclosed in the specification or its equivalents.

As for the second contention relating to the connector, the applicants argue that while it is agreed that the wires 7 and 8 must be connected to the device, the patent does not discuss use of an actual connector. Whether or not Cunningham actually discusses a connector is a moot point since by the applicants' own admission, a connector of some sort is required to make the device of Cunningham operative. A connector is therefore considered inherent. As for the particular type of connector, the amended claims now call for a connector configured for removable attachment of the motion sensor unit to the electronic device. The examiner takes Official Notice that there are literally hundreds of prior art cardiac treatment devices that employ connectors configured for removable attachment to the electronic implant housing. As stated above, such a feature is a well-known, well-recognized, industry standard.

#### ***Allowable Subject Matter***

4. Claims 29-31, 39 and 40 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

There is no teaching in the prior art of record for modifying the lead of Cunningham to contain a second concentric cylindrical lead with conductive means for sensing cardiac electrical activity.

**Conclusion**

5. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

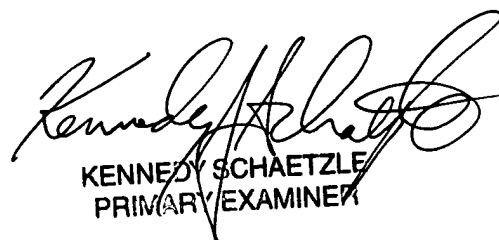
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kennedy Schaetzle whose telephone number is 571 272-4954. The examiner can normally be reached M-W and F from 9:30 -6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached M-F at 571 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

KJS  
March 11, 2005

  
KENNEDY SCHAETZLE  
PRIMARY EXAMINER